

CLAIMS

1. An expandable balloon for use in angioplasty procedures, comprising a balloon having an outer surface layer, the outer surface layer being made from electrospun nanofibers and incorporating at least one pharmaceutically active substance.
- 5 2. A balloon according to claim 1, further comprising an intermediate layer formed between the balloon and the outer surface layer, the intermediate layer being formed by dip-coating.
3. A balloon according to claim 1 or 2, wherein the outer surface layer is formed on a separate flexible tube and the outer surface layer is slipped over the balloon.
- 10 4. A balloon according to claim 3, wherein the flexible tube is folded, so that the flexible tube, when seen in cross-section, defines a spoke-and-hub-formation.
- 15 5. A balloon according to any of claims 1-4, wherein the pharmaceutically active substance comprises nitric oxide, and wherein the outer surface layer further includes an acidic agent.
6. A balloon according to any of claims 1-5, wherein the outer surface layer is essentially made from a polymer matrix, which contains molecules capable of releasing the at least one pharmaceutically active substance.
- 20 7. A balloon according to claim 6, wherein the outer surface layer is essentially made from a polymeric linear poly(ethylenimine) diazeniumdiolate.
8. A balloon according to any of claims 1-7, wherein the pharmaceutically active substance is provided in the form of biodegradable beadings distributed between the nanofibers.
- 25 9. A kit comprising a stent and a coated balloon according to any of the preceding claims for expanding the stent.
10. A kit according to claim 9, further comprising a guide wire for guiding the stent to a treatment site in tubular structures of a living being.
- 30 11. A kit according to claim 10, wherein the guide wire is provided with a coating.
12. A method of producing a balloon for use in angioplasty, the method comprising the step of forming an outer surface layer for the balloon by electrospinning of nanofibers, the outer surface layer containing at least one pharmaceutically active substance.
- 35 13. A method according to claim 12, wherein the outer surface layer is applied in the unexpanded state of the balloon.

14. A method according to claim 12 or 13, further comprising, prior to the step of forming the outer surface layer, a step of dip-coating the balloon to form an intermediate layer.

- 5 15. A method according to any of claims 12-14, comprising:
- forming the outer surface layer on a separate flexible tube;
 - slipping the flexible tube over the balloon.

- 10 16. A method according to claim 15, wherein the step of forming the outer surface layer on the flexible tube comprises:
- providing at least one core member;
 - forming the flexible tube with the outer surface layer by electrospinning the nanofibers onto an outer surface of the core member.

- 15 17. A method according to claim 15 or 16, further comprising, subsequent to the step of slipping the flexible tube over the balloon, folding the flexible tube, so that the flexible tube, when seen in cross-section, defines a spoke-and-hub-formation.

- 20 18. A method according to any of claims 12-17, wherein the pharmaceutically active substance comprises nitric oxide.

19. A method according to claim 18, wherein the outer surface layer further comprises an acidic agent.

- 25 20. A method according to any of claims 12-19, wherein the outer surface layer is essentially made from a polymer matrix, which contains molecules capable of releasing the at least one pharmaceutically active substance.

- 30 21. A method according to claim 20, wherein the outer surface layer is essentially made from a polymeric linear poly(ethylenimine) diazeniumdiolate.

- 35 22. A method according to any of claims 18-21, wherein nitric oxide is applied to the outer surface layer by exposing the outer surface layer to nitric oxide in a chamber containing pressurized nitric oxide.

23. A method according to claim 22, wherein nitric oxide is applied in the expanded state of the balloon.

- 40 24. A method according to claim 15 and 22, wherein nitric oxide is applied before the flexible tube is slipped over the balloon, and wherein the flexible tube is supported by a core member in said chamber.

25. A method according to any of claims 22-24, wherein the balloon is exposed to nitric oxide at a pressure of 1-5 bar in said chamber.

26. A method according to any of claims 12-25, wherein the step of electrospinning nanofibers comprises feeding a fiber-forming material through a dispensing electrode arranged at a distance from a supporting element, whereby a plurality of strands of the fiber-forming material emerge out of said dispensing electrode, the method comprising controlling the properties of the outer surface layer by controlling the fluidity of said strands when they reach the supporting element.
27. A method according to claim 26, wherein the fluidity of the strands when they reach the supporting element is controlled by controlling the distance between dispensing electrode and the supporting element.
27. Use of an acidic agent as catalyst for the release of nitric oxide in a balloon according to any of claims 1-8.
28. A method of treating cell disorders in tubular structures of a living being, comprising the steps of:
- placing a balloon according to any of claims 1-8 at a treatment site within the tubular structures;
 - expanding the balloon at the treatment site;
 - releasing the pharmaceutically active substance at the treatment site.
29. A method according to claim 28, wherein the step of releasing is controlled by the presence of a ph-controlling substance contained in the outer surface layer.
30. A method according to claim 28 or 29, further comprising, prior to the step of placing the balloon, placing an unexpanded stent on the balloon; and placing the stent at the treatment site along with the balloon; and subsequently expanding the stent at the treatment site as the balloon is being expanded; and subsequently deflating the balloon and removing it from the tubular structure while the stent is left at the treatment site.